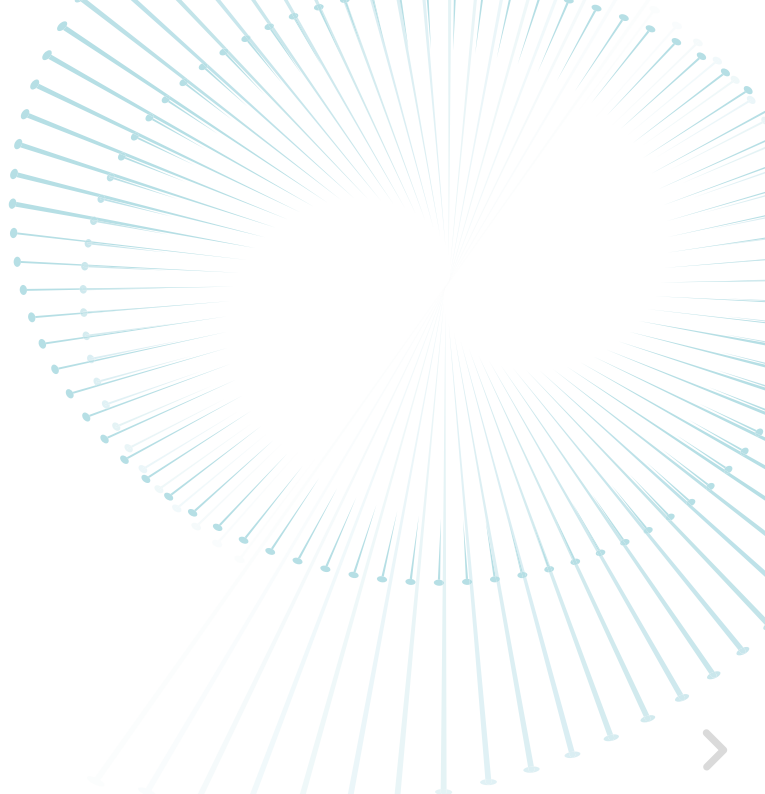


PRODUCT LIST

2022





GENERICs FDFs

Available Dossiers

Dossiers Under Development

Dossiers Under Consideration

GENERICs APIs

Available Portfolio - Malta

Available Portfolio - Spain

Under Development

CHLORHEXIDINE AND OTHER ANTISEPTICS

APIs

FDFs





AVAILABLE DOSSIERS

MOLECULE	PHARMACEUTICAL FORM & STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER STATUS
 Apixaban	Film-coated tablets 2,5 mg, 5 mg	Eliquis® BMS/Pfizer	Stroke and systemic embolism Deep vein thrombosis and pulmonary embolism	Approved: US, EU, UK
Captopril	Tablets 12,5 mg, 25 mg, 50 mg, 100 mg	Captopril Mylan	Hypertension Heart failure	Approved: US
Daptomycin	Powder for solution for injection or infusion in glass vial 350 mg, 500 mg	Cubicin® Merck	Skin and soft-tissue infections Endocarditis	Approved: CA, EU, UK, KR, UA, AU Filed: ZA
 Mirtazapine	Tablets 7,5 mg*, 15 mg, 30 mg and 45 mg	Remeron® Organon	Major depression	Approved: EU* Filed: US
 Prucalopride Succinate	Film-coated tablets 1 mg, 2 mg	Resotrans® Janssen Resolor® Shire	Chronic constipation	Approved: EU and UK, US filing NCE: Dec'23
 Rivaroxaban	Film-coated tablets 2,5 mg, 10 mg, 15 mg, 20 mg	Xarelto® Bayer	Stroke and systemic embolism Deep vein thrombosis and pulmonary embolism	Approved: EU, CIS Filed: IL, MX
Sodium Oxybate	Oral Solution in bottle 300 mg/ml	Xyrem® UCB Pharma	Narcolepsy	Approved: EU
 Sugammadex Sodium	Solution for injection 200 mg / 2 ml 500 mg / 5 ml	Bridion® MSD	Reversal of neuromuscular blockade in anesthesia	Approved: EU, UK, NZ Filed: IL, MX, SEA
 Sunitinib Maleate	Capsules 12,5 mg, 25 mg, 37,5 mg, 50 mg	Sutent® Pfizer	Renal carcinoma, pancreatic and stromal tumors	Approved: EU, KSA Filed: MX, JO
Thalidomide	Capsules 50 mg	Thalidomid Celgene® Celgene	Multiple myeloma	Approved: EU, UK
Tobramycin	Nebulizer solution in plastic ampoule blow-fill-seal 300 mg / 5 ml	Tobi® Novartis	Cystic fibrosis	Approved: AU, EU, UK, BR, PA, GT, NZ, US



DOSSIERS UNDER DEVELOPMENT

	MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
	Axitinib	Film coated tablets	1 mg and 5 mg	Inlyta®	Advance renal cell carcinoma	(US only) Q4 2023
HP	Dexmedetomidine	Infusion bag	4 mcg/ml	Precedex® Pfizer	Sedation of patients during treatment in intensive care	Q4 2022 (Ready for filling)
	Edaravone	Solution for infusion	30 mg / 100 ml 60 mg / 100 ml	Radicava® Mitsubishi Tanabe	Amyotrophic lateral sclerosis	Q4 2022 (Ready for filling)
	Ivacaftor	Film coated tablets	150 mg and 75 mg (only in EU)	Kalydeco®	Cystic fibrosis	Q2 2025
	Lofexidine	Film coated tablets	0,18 mg	Lucemyra®	Opioid withdrawal	Q1 2024
	Revefenacin	Solution for inhalation	175 mcg / 3 ml	Yupelri® Mylan	Chronic obstructive pulmonary disease (COPD)	Q4 2022 (NCE-1)
	Ruxolitinib	Tablets	5 mg, 10 mg, 15 mg, 20 mg and 25 mg	Jakavi ® (EU) Jakafi ® (US)	Myelofibrosis, polycythemia vera	Q2 2024
	Varenicline L-tartrate	Tablets	0,5 mg and 1 mg	Chantix®, Champix® Pfizer	Smoking cessation	Q4 2022
	Voclosporin	Soft gel capsules	7,9 mg	Lupkynis®	Lupus Nephritis	Q1 2025 (NCE-1)



DOSSIERS UNDER CONSIDERATION

MOLECULE	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	INDICATION
Cladribine	Tablets	10 mg	Mavenclad	Multiple sclerosis
Fluvoxamine XR	Capsules extended release	100 and 150 mg	Luvox XR	Obsessive compulsive disorder
Mesalazine XR	Tablets	1,2 g	Lialda	Ulcerative colitis
Ruxolitinib Phosphate	Cream	1,5%	Opzelura	Atopic dermatitis
Tofacitinib IR	Film coated tablets	5 mg and 10 mg	Xeljanz®	Rheumatoid arthritis
Tofacitinib XR	Extended release tablets	11 mg and 22 mg	Xeljanz XR®	Rheumatoid arthritis



AVAILABLE PORTFOLIO - MALTA

 Apixaban	Micafungin Sodium	 Sugammadex Sodium
Cinacalcet HCl	 Prucalopride	 Sunitinib Malate
Desvenlafaxine Succinate	Rasagiline Tartrate	Vildagliptin
 Edaravone	 Rivaroxaban	
 Lofexidine	Solifenacin Succinate	

AVAILABLE PORTFOLIO - SPAIN

Adapalene	Guanfacine HCl	Olopatadine HCl
Brimonidine Tartrate	Lamotrigine	Paroxetine HCl
Clozapine	Loxapine Base	Pazopanib
Cyclobenzaprine HCl	Loxapine Succinate	Pimecrolimus
Desvenlafaxine Base	Mexiletine HCl	Quetiapine Fumarate
Felodipine	 Mirtazapine	 Varenicline L-tartrate
Fluvoxamine Maleate	Nepafenac [sterile and non sterile]	



UNDER DEVELOPMENT

	ACTIVE PHARMACEUTICAL INGREDIENT	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS
	Ivacaftor	Kalydeco®	Cystic fibrosis	DMF Q4 2024
	Lumacaftor	Orkambi®	Cystic fibrosis	DMF Q2 2026
	Elexacaftor	Trikafta® (US) and Kaftrio® (EU)	Cystic fibrosis	DMF Q2 2026
	Opicapone	Ongentys®	“Off” episodes in Parkinson	DMF Q3 2023
	Relugolix	Orgovyx®	Prostate cancer and uterine fibroid bleeding	DMF Q4 2023
	Revefenacin	Yupelri®, Theravance Biopharma	Chronic obstructive pulmonary disease (COPD)	DMF Available for Reference
	Ruxolitinib	Jakafi®, Novartis	Myelofibrosis, polycythemia vera	DMF Q3 2023
	Tezacaftor	Symdeko® (US) and Symkevi® (EU)	Cystic fibrosis	DMF Q4 2024
	Voclosporin	Lupkynis®	Lupus Nephritis	DMF Q1 2024



CHLORHEXIDINE AND OTHER ANTISEPTICS

APIs

API - ANTISEPTICS - AVAILABLE

Chlorhexidine Base		Chlorhexidine Diacetate	CEP
Chlorhexidine Digluconate 20% Solution	CEP	Chlorhexidine Dihydrochloride	CEP
Octenidine Dihydrochloride	DMF		

FDFs - PHARMACEUTICAL GRADE

CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE	
Hydroalcoholic solution Transparent	0,50%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request

CHLORHEXIDINE DIGLUCONATE - UNDER DEVELOPMENT DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE	
Hydroalcoholic solution Coloured	0,50%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request
Hydroalcoholic solution Transparent and coloured	2%	Plastic bottles	30 ml, 100 ml, 250 ml More formats on request



CHLORHEXIDINE AND OTHER ANTISEPTICS

FDFs - PHARMACEUTICAL GRADE

OCTENIDINE DIHYDROCHLORIDE - UNDER DEVELOPMENT DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE		REFERENCE PRODUCT
Spray	2% phenoxyethanol + 0,1% octenidine	Plastic bottles	50ml	Octenisept



FDFs - COSMETIC GRADE

OCTENIDINE DIHYDROCHLORIDE - UNDER DEVELOPMENT DOSSIERS

PRODUCT	FORMATS AVAILABLE		INDICATION
Cream	Bottle with pump biodegradable	500ml	Coadyudant for atopic dermatitis



CHLORHEXIDINE AND OTHER ANTISEPTICS

FDFs - BIOCIDES GRADE

CHLORHEXIDINE DIGLUCONATE - AVAILABLE DOSSIERS

PRODUCT	STRENGTH	FORMATS AVAILABLE	
Hydroalcoholic solution Transparent and coloured	2%	Plastic bottles	60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml
	0,50%		More formats on request
Aqueous solution	2%	Blow-fill-seal ampoules and plastic bottles	Single dose (10 ml), 60 ml, 75 ml, 100 ml, 125 ml, 250 ml, 500 ml
	0,50%		10 ml, 60 ml, 75 ml
Wipes		Individual sachet	
Aqueous	2%	Flow pack of 8 wipes	20 x 20 cm, 6 x 7 cm
Alcoholic		Individual sachet	
Hand scrub			
Transparent	4%	HDPE bottles with dosing pump	20 ml, 500 ml, 1000 ml

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